EXHIBIT A

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Food & Drug Administration New England District One Montvale Avenue, 4th Floor Stoneham, MA 02180 Phone: (781) 587-7500 Industry Information: www.fda.gov/oc/industry	02/01/2016 - 02/05/2016, 02/11/2016
	FEI NUMBER 3008477155

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Amarpreet Singh Sawhney, President, CEO, and Chairman of the Board

FIRM NAME	STREET ADDRESS
Ocular Therapeutix, Inc.	36 Crosby Drive, Suite 101
CITY, STATE AND ZIP CODE Bedford, MA 01730	TYPE OF ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

Laboratory records do not include a complete record of all data secured in the course of each test, including all spectra from laboratory instrumentation, properly identified to show the lot tested and drug product tested.

Specifically:

A. Review of your firm's source documentation for analytical data submitted in NDA (b) (4) [(b) (4)] supporting exhibit batches (b) (4) found that printed HPLC chromatograms and integration results for dose content uniformity and purity were discarded following (b) (4) and only the reprocessed data was printed and retained. For example:

a. Review of source dose content uniformity data for (b) (4) , Exhibit Lot # (b) (4) included in the submission for (b) (4) revealed that (b) (4) were reprocessed and the original printed chromatograms and integration results were discarded.

b. Review of source dose content uniformity data for (b) (4) , Exhibit Lot # (b) (4) included in the submission for (b) (4) vealed that (b) (4) were reprocessed and the original printed chromatograms and integration results were discarded.

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c. Review of source dose content uniformity data for (b) (4), Exhibit Lot # (b) (4) included in the submission for (b) (4) revealed that (b) (4) runs were reprocessed and the original printed chromatograms and integration results were discarded.

d. Review of source purity data for (b) (4) Exhibit Lot # (b) (4) included in the submission for NDA (b) (4) revealed that (b) (4) runs were reprocessed and the original printed chromatograms and integration results were discarded.

In each case there was no documented explanation for (b) (4) to support the replacement of original source data with reprocessed chromatograms.

B. 1. Review of the reprocessed (b) (4) for purity analysis of (b) (4) (b) (4) Exhibit Lot # (b) (4) supporting data submitted in (b) (4) revealed a failure to include the area of a typical peak of unknown impurity at a retention time of (b) (4) in the total area and content of unknown impurities.

B. 2. Review of the (b) (4) for purity analysis of (b) (4) Stability Lot (b) (4) test point, supporting data submitted in (b) (4) revealed a failure to include the area (b) (4) of approximately (b) (4) in the total area and content of unknown impurities.

C. Review of source dose content uniformity data for (b) (4) Exhibit Lot # (b) (4) included in the submission for NDA (b) (4) found that this analysis was performed on (b) (4) Review of the raw data found sets printed on different dates 11/07/2013 and 11/26/2013. No documentation was provided to explain why (b) (4) were processed and printed on 11/26/2013 while (b) (4) were all printed on 11/07/2013 or what happened to the original data sheets printed on 11/07/2013.

D. You do not have written procedures to clearly specify how manual integration of chromatograms is performed.

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Observation 2

Samples taken of drug products for determination of conformance to written specifications are not representative.

Specifically: Your sampling plan supporting product release and stability testing (b) (4) (b) (4) is not designed to assure that samples are representative of the entire subject lot or unit to be tested. Your procedure SOP 1004, Revision: C, Release of Drug Products, states that product sampling for LAL testing "should result in a random sampling of a finished production lot" and product sampling for performance testing is non-specific regarding the sampling technique. Your procedure does not include any explanation of sampling techniques or sampling distribution assured to obtain representative samples. Additionally, there were no documented sample records (b) (4) exhibit batches (b) (4) (b) (4) (b) (4) showing the sampling distribution and that sampling was representative of the complete lots to support data submitted in NDA (b) (4) (b) (4)

Observation 3

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically:
A. Control procedures fail to include adequacy of mixing to assure uniformity and homogeneity of the (b) (4) (b) (4)) as part of the bulk preparation (b) (4)

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(b) (4) Operators (b) (4) to a (b) (4) dpoint. Th (b) (4) therefore may challenge adequate determination of a (b) (4) endpoint for (b) (4)

B. In-process testing o (b) (4) drug product does not include evaluation (b) (4) prior to terminal sterilization despite that elevated (b) (4) n the drug product may have a detrimental effect on product quality when exposed to the (b) (4) rocess.

C. Preparation of (b) (4), used to (b) (4) (b) (4) drug product strands includes (b) (4) On 02/03/2016, we observed that the (b) (4) (b) (4) Lot # (b) (4) according to master batch record (b) (4) contained (b) (4) by the (b) (4) during (b) (4) The amount o (b) (4) n the (b) (4) is not controlled, quantified, or optimized in relation to potential effects on the product including drug content uniformity or drying properties.

D. You do not characterize and trend rejects produced during inspection of drug product using the (b) (4) system, Equipment (b) (4) batch record. Additionally, a (b) (4) dosage form may not be accomplished therefore potentially missing detection of voids and other defects that may affect drug content or other quality attributes.

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Observation 4

Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of manufacturing of the drug product.

Specifically: The current (b) (4) commercial batch size (b) (4) units, submitted in (b) (4) does not conform to the formulated bulk drug quantity which theoretically may produ (b) (4) is discrepancy results in a lack of accountability for the full formulated batch quantity, quality, and finished drug yield.

Observation 5

Written production and control procedures include batches formulated with the intent to provide (b) (4) percent of the labeled or established amount of active ingredient.

Specifically: The (b) (4) (b) (4) input to drug product formulation is not calculated based on the specific lot assay value. You have not evaluated API input at the acceptable low end of the batch record specified quantity range for input and API assay at the low end of the acceptable range for release. Also, you have not evaluated API input at the acceptable high end of the batch record specified quantity range for input and API assay at the high end of the acceptable range for release.

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Observation 6

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically:
A. Testing and release specifications for (b) (4) ug product strands do not include assessment of the (b) (4) ecessary to assure (b) (4) critical to achieving finished drug product (b) (4) requirements and (b) (4) uniformity.

B. (b) (4) used in (b) (4) (b) (4) drug product contact operations in th (b) (4) he product and packaging components is not sampled and tested for identification or any other quality attributes. Additionally, there is no system to record the lot identification (b) (4) sed in the production of specific product lots.

C. A written procedure was not available to prescribe your handling of invalid laboratory data shown to have an assignable root cause for the discrepancy.

Observation 7

Equipment for adequate control over air pressure, micro-organisms, humidity, and temperature is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically:
A. The temperature and humidity in th (b) (4) used to produce (b) (4) (b) (4) is not monitored to assure that conditions are appropriate for

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production operations throughout the process including product [redacted] steps.

B. The [redacted] cleanroom facility [redacted] used to produce [redacted] s from the [redacted] owning room to the [redacted] production room meaning that airborne contaminants in the gowning room may be swept into the production room when the door is opened for personnel and equipment entry and exit.

C. The [redacted], and [redacted] in the incubators used to [redacted] drug product are not monitored at a frequency designated to assure that appropriate conditions are maintained throughout the operation.

D. The [redacted] used to [redacted] drug product and [redacted] re not monitored at a frequency designated to assure that appropriate conditions are maintained throughout the operation.

Observation 8

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically:

A. The maximum hold time for [redacted] drug product produced prior to terminal sterilization has not been established or controlled.

B. There is no documentation or control of the [redacted] drug product time outside refrigeration during manufacturing operations.

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Observation 9

Unauthorized personnel have access to enter areas of the buildings and facilities designated as limited access areas.

Specifically:
A. On 02/01/2016 we observed that your receiving / shipping bay is shared with another tenant of the building and the door leading to production areas from the receiving bay is not locked or otherwise secured from unauthorized access. At the same time we observed (b) (4) driver enter the production facility, unchallenged, through the receiving bay.

B. On 02/01/2016, we observed that the (b) (4) (b) (4) used in drug product contact operations to manufacture (b) (4) was unsecured and open so that the filling port could potentially be accessed by unauthorized personnel.

Observation 10

Buildings used in the manufacturing of a drug product are not maintained in a good state of repair.

Specifically: On 02/01/2016, we observed gaps up to approximately two centimeters under the receiving / shipping bay doors. We also observed numerous scrap corrugate, wood, and plastic packaging materials piled in the receiving / shipping bay in the corner and along the walls providing potential harborage to pests.

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